K100823/~~A2~~ S3

Page 1/7

JAN 24 2011

510(k) Summary

Applicant: Accuro Medical, 2655 Wisconsin Avenue, Downers Grove, IL 60515

FDA CDRH DMC
DEC 27 2010
Received

Traditional 510(k) Submission for Accuro Medical WoundPro Apex

Date: 12/3/2010

E-13

Section E - 510(k) Summary
This 510(k) Summary for Accuro Medical WoundPro Apex meets the requirements of 21 CFR 807.92.

1 Sponsor's Name, Address and Contact Person

Contact for Submission:
Todd Hubbard
CEO Accuro Medical Products LLC
2655 Wisconsin Avenue
Downers Grove, IL 60515
Tel: (630) 829-1675
Fax: (630) 829-1677
Email: todd.hubbard@accuromedical.com

Sponsor:
Accuro Medical Products LLC
2655 Wisconsin Avenue
Downers Grove, IL 60515
Contact: Tim Costa
Telephone: 630-829-1631
FDA Registration# 3007793449

2 Name of Device

Trade Name: Wound Pro Apex

Common Name: Powered Suction Pump

Classification Name: Negative Pressure Wound Therapy Suction Pump

Product Code: OMP (class 2, 21 CFR 878.4780)

3 Name of the Predicate Device(s)

Medela Invia – K080357
Blue Sky Vista– K061367

4 Device Description

The Apex is part of the Wound Pro family of products offered by Accuro Medical Products LLC.

The Apex is a powered suction pump that uses controlled negative pressure. The control unit incorporates a maintenance free brushless DC motor and is powered by a rechargeable battery power source. Optionally the unit can be connected to mains power using the included Medical Grade Switching power converter.

Apex has a negative pressure setting range of 20mm to 150mmHg which is electronically monitored and controlled. The pump includes push button user interface controls and an electronic display with audible and visual alarm indicators.

The device can accommodate 300cc and 800cc canister sizes.

The unit can be operated on a countertop and has provisions for connection to IV poles, bed side rails, or footboard mounting.

The unit may be sold individually or as part of a system. The system includes the following items:

- 1 Apex NPWT Pump
- 1 Mounting Clamp for IV Pole, Bedrail, or Footboard mounting
- 1 Hospital grade Charging Connection to 110V power source
- 1 Medium (flat drain) dressing kit. Kit includes:
  - Non-adherent contact layer
  - Anti-bacterial Gauze
  - Drain Tube
  - Drain Clamp
  - Cover Dressing
  - Instructions for use
- 1 Disposable 300cc Canister
- 1 Canister Tubing Set. Set includes:
  - Dual lumen Tubing (runs between the canister and the connector)
  - Clamp
  - Connector for attachment to dual lumen tube to the drain
- Carrying Case

System Specifications:

Feature	Specification
Weight – Control Unit	3.8 lbs (1.7 Kg)
Dimensions	6 3/4"(w) x 8 1/2" (h) x 3 1/2" (d) (17 x 21 x 9 cm)
Electrical - Battery Powered Optional connection to mains power	18VDC 25 Watts Medical Grade Switching Power Adapter Model: TR30RAM180 Input: 90-264VAC, 0.8-0.4A, 47-63Hz Output: 18VDC 1.67A
Collection Canister	300cc and 800cc
Modes – Continuous and Intermittent Therapy	20 – 150mmHg Vacuum

5 Indications for Use

The WoundPro Apex Negative Pressure Wound Therapy System may promote wound healing, through the drainage and removal of infectious material and other fluids from the wound site using continuous and/or intermittent negative pressure. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts may benefit from the use of this device. The WoundPro Apex is intended for use in a healthcare facility only.

Types of Wounds Indicated are:

- Diabetic/Neuropathic ulcers
- Pressure ulcers
- Chronic wounds
- Acute wounds
- Dehisced wounds

Accuro Medical

510(k) Summary

6 Technological Characteristics

Comparison Chart

	Accuro Medical	Medela	BlueSky Vista
Indications for Use	The WoundPro Apex Negative Pressure Wound Therapy System may promote wound healing, through the drainage and removal of infectious material and other fluids from the wound site using continuous and/or intermittent negative pressure. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts may benefit from the use of this device. Types of Wounds Indicated are: • Diabetic/Neuropathic ulcers • Pressure ulcers • Chronic wounds • Acute wounds • Dehisced wounds	The Medela INVIA Wound Therapy is indicated to help promote wound healing, through means including drainage and removal of infectious material and other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute, and dehisced wounds, partial thickness burns, ulcers (such as diabetic or pressure), flaps or grafts. Types of Wounds Indicated are: • Diabetic/Neuropathic ulcers • Pressure ulcers • Chronic wounds • Acute wounds • Dehisced wounds	The Blue Sky Vista Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.
Weight	3.8 lbs (1.7 Kg)	<2.2 lbs	4.3 lbs
Dimensions	6 3/4"(w) x 8 1/2" (h) x 3 1/2" (d) (17 x 21 x 9 cm)	3.74" x 6.69" x 6.91" 150mm x 170mm x 95mm	10.2" x 9.8" x 4.2" 260mm x 250mm x 106mm
Power Source	Lithium Ion Battery AC Power	Lithium Ion Battery AC power	Nickel Metal Hydride Battery AC Power
Electrical Voltage	90-260VAC 47-63Hz	100-240V AC 47-63Hz	100-240V AC 50-60 Hz

510(k) Summary

	Accuro Medical	Medela	Blue Sky Vista
Electrical Amperage	.8-.4A	.8-.4A	1.0A
Housing	Injection molded plastic	Injection molded plastic	Vacuum molded plastic
Vacuum Range	20-150mm Hg	60-200mm Hg	Up to 200mm Hg
Suction Capacity	5 L/min	5 L/min	8 L/min
Canister Volumes	0.3 L / 0.8 L	0.3 L / 0.8 L	0.25 L / 0.8 L
Modes	Continuous or Variable / Intermittent Modes	Continuous or Intermittent Mode	Continuous
Filter	Hydrophobic overflow protection / bacteria filter integrated into the single use collection canister	Hydrophobic overflow protection / bacteria / odor filter integrated into the single use collection canister	Single Patient Antibacterial Filter

Summary of Technological Characteristics as Compared to Predicate Devices

The Apex is compliant with all electrical safety requirements including IEC 60601-1 and IEC 60601-1-2.

The Apex pump's mechanical performance characteristics are substantially equivalent to the predicate devices and other legally marketed devices.

The technology used in the Apex pump is substantially equivalent to the predicate devices and other legally marketed devices.

The materials used in construction of the Apex are substantially equivalent to the predicate devices and other legally marketed devices.

While there are slight differences, the Apex's weight, dimensions, and power source are substantially equivalent to the predicate devices and other legally marketed devices.

The Apex is substantially equivalent to the predicate devices and other legally marketed devices with regards to vacuum range, suction capacity, canister volume, and modes of operation.

The Apex and the predicate devices are substantially equivalent with regards to indications for use and patient contact materials. All three devices utilize off-the-shelf sterile wound dressing materials composed of biocompatible materials.

The technological features in the WoundPro Apex do not affect the safety and effectiveness of this device.

7 Performance Data

The subject device was subjected to and passed all non-clinical testing including:

- Electrical safety
- Electromagnetic compatibility (EMC)
- Software validation
- Accuracy of Canister Volume Marks
- Testing of filters ability to shut fluid flow off when it gets wet (compare to predicate devices)
- Test ability of tubing clamp and cap to keep fluid from leaking out of tubing (compare to predicate devices).
- Test batteries to determine how long they will last on a completely sealed wound (compared to predicate devices).
- Test ability of the system to maintain a consistent vacuum running on batteries until all battery power is depleted and the unit shuts down (compared to predicate devices).
- Vacuum Setting Accuracy testing at different vacuum setting (comparing to predicate devices).
- Fluid Extraction Test comparing fluid volumes removed from simulated wound at different flow rates and different vacuum settings (compared to predicate devices).

8 Conclusion

All conclusions are made in accordance with the decision making process recommendations as outlined in the 510(k) SE Decision Making Process document.

The Accuro Medical Products WoundPro Apex's intended uses are substantially equivalent to the predicate devices.

The technological characteristics and components used to build the Accuro Medical Products WoundPro Apex are all substantially equivalent to the two predicate devices.

The performance and technology of the WoundPro Apex are substantially equivalent to the predicate devices.

At no time does the subject device perform inferiorly to the predicate devices.

It is our belief that the information submitted supports our claim that the Accuro Medical Products WoundPro Apex is substantially equivalent to the two predicate devices and other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Accuro Medical Products, LLC
% Mr. Todd Hubbard
CEO/President
3879 East 120th Avenue, Suite 328
Denver, Colorado 80233

JAN 24 2011

Re: K100823
Trade/Device Name: Wound Pro Apex
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: OMP
Dated: December 17, 2010
Received: December 27, 2010

Dear Mr. Hubbard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K100823

Device Name: Wound Pro Apex

Indications for use:

The WoundPro Apex Negative Pressure Wound Therapy System may promote wound healing, through the drainage and removal of infectious material and other fluids from the wound site using continuous and/or intermittent negative pressure. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts may benefit from the use of this device. The WoundPro Apex is intended for use in a healthcare facility only.

Types of Wounds Indicated are:

- Diabetic/Neuropathic ulcers
- Pressure ulcers
- Chronic wounds
- Acute wounds
- Dehisced wounds

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100823